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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,838	02/08/2005	Stephen Robert Wedge	056291-5199	2361

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EXAMINER	
STONE, CHRISTOPHER R	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
07/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,838	WEDGE, STEPHEN ROBERT	
	Examiner	Art Unit	
	CHRISTOPHER R. STONE	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,15 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,15 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed April 15, 2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hennequin et al (WO 01/32651) in view Magne et al.

Claims 1-6, 15 and 16 are drawn to a method for the treatment of cancer and a method for the production of an antiangiogenic and/or vascular permeability reducing effect in a warm-blooded animal, which comprises administering ZD6474 and ZD1839, optionally with an effective amount of ionizing radiation. Claims 7 and 8 are drawn to a pharmaceutical composition and kit comprising ZD6474 and ZD1839.

Hennequin et al discloses a method for the treatment of cancer, solid tumors in particular, (p.28, lines 11-17), including a human non-small cell lung cancer (CaLu-6, p. 22, example c) and a method for the production of an antiangiogenic and/or vascular permeability reducing effect in a warm-blooded animal (p. 26, lines 10-

14), which comprises administering a compound of formula I (p. 3). ZD6474 is specifically identified as a compound of Formula I (claim 8). Hennequin et al further teaches that this treatment may additionally include radiotherapy administered simultaneously, sequentially or separately (p. 26, lines 22-30). Hennequin et al does not teach this method of treatment further comprising the administration of ZD1839.

Magne et al teaches that ZD1839 (Iressa) enhances the growth inhibitory effect of other cytotoxic drugs (p. 825, second column). Magni et al further teaches that ZD1839 is a strong radiosensitizer as well as chemosensitizer (p. 826, first column). Therefore it would have been obvious to one of ordinary skill in the art at the time of the instantly claimed invention to add the step of administrating ZD1839 to the method of treatment described in Hennequin et al, because of its known chemosenstizing and radiosensitizing activity, thus resulting in the practice of the instantly claimed invention with a reasonable expectation of success. Furthermore, combining ZD6474 and ZD1839 into a pharmaceutical composition or kit would have been obvious to one of ordinary skill in the art at the time of the invention, since they were both known chemotherapeutic agents. Applicant is reminded of in re Kerkhoven, which affirmed that "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ....[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) The addition of a pharmaceutically acceptable carrier or excipient to the aforementioned pharmaceutical composition would

have been obvious to one of ordinary skill in the art at the time of the invention to allow for effective administration to the patient and delivery to the targeted tissue.

Applicant argues that there is no motivation to combine ZD6474 with ZD1839. This is not found to be persuasive because, as noted above, ZD6474 is explicitly disclosed in Hennequin et al as a preferred embodiment. In fact it is the only compound in claim 8. Furthermore, as Applicant notes on page 6 of the response filed April 15, 2008, Hennequin et al explicitly teaches the combination of ZD6474 with tyrosine kinase inhibitors, a class of compounds of which ZD1839 is a known member. This provides the motivation to one of ordinary skill in the art at the time of the instantly claimed invention to combine the two compounds in the treatment of cancer with a reasonable expectation of success. Applicant further argues that there are surprising beneficial results when using the instantly claimed combination of ZD6474 and ZD1839. This is an allegation without factual support and is therefore unpersuasive. The data on pages 17 and 18 demonstrates the expected approximately additive result. In fact, the data in Table I of p. 17, appears to demonstrate less than additive results.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER R. STONE whose telephone number is (571)270-3494. The examiner can normally be reached on Monday-Thursday, 7:30am-4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

03July2008
CRS

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614